

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

ROBERTS et al.

Group Art Unit: 1754

Application Serial No. 09/508,923

Examiner: VANOVY, T.

Filed: JUNE 19, 2000

Title: METAL COMPOUNDS, MIXED OR SULPHATED, AS PHOSPHATE BINDERS

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AMENDMENT AND REPLY

Hon. Commissioner of Patents
Washington, D.C. 20231

Sir:

In response to the Office Action dated October 22, 2001, please amend the above identified application as follows herein.

In the Specification:

Page 1, delete the whole paragraph starting in line 11, and replace it with the following new paragraph:

--In patients with kidney failure on haemodialysis (of whom there are 6,000,000 world wide), phosphate concentrations in the blood plasma can rise dramatically and such hyperphosphataemia can result in calcium phosphate deposition in soft tissue. Currently, the plasma phosphate levels are reduced by oral intake of inorganic and organic phosphate binders. The most common treatment in the UK is with aluminum hydroxide gel ("ALUDROX®" at 4 g/day) which forms an insoluble aluminum phosphate. However, this results in further toxic complications due to Al accumulation, eg reduction in haemoglobin production, impairment in natural repair and production of bone and possible impairment of neurological/cognitive function. Improvements in phosphate binding capacity as compared with aluminum hydroxide gel have been achieved with other aluminum compounds such as microcrystalline aluminum oxide hydroxide (boehmite) and certain hydrotalcites have been made; Ookubo et al, Journal Pharmaceutical Sciences (November 1992), 81(11), 1139-1140. However, such compounds still result in an intolerable amount of aluminum accumulation in